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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,445	11/16/2001	Ernest G. Schutt	ALLIA.62F1C1C1	3983
20995	7590	07/01/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			SHARAREH, SHAHNAM J	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/991,445	<b>Applicant(s)</b> SCHUTT ET AL.	
	<b>Examiner</b> Shahnam Sharareh	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 8, 11 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-10, 12-15, 17-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's response filed on April 14, 2004 has been entered. Claims 1-20 are pending.
2. Applicant has made an election of species in Paper No. 6. Accordingly, perfluorobutane was elected as the species for fluorocarbons and oxygen was elected as the species for the modifier gas. Claims 1-7, 9-10, 12-15, 17-20 read on the elected species. Claims 8, 11, 16 are withdrawn from further consideration as they are not directed to elected species.

This application contains claims 8, 11, 16 drawn to an invention nonelected species with traverse in the Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's reservation of the right to petition the restriction requirement is acknowledged.

### ***Double Patenting***

3. Claims 1-7, 9-10, 12-15, 17-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of 1-12 of US Patent 6,372,195, claims 1-101 of US Patent 6,258,339, claims 1-24 of US Patent 5,695,741, claims 1-38 of US Patent 5,639,443, and claims 17-22 of US Patent 5,798,091, claims 1-9, 38-73 of US Patent 5,804,162, claims 26-51 of US Patent 6,193,952.

Applicant's request to revisit this rejection after the claims have been formally allowed is noted. Claims, however, stand rejected for the reasons of record.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-6, 9-10, 13-15, 17-18, 20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider et al US Patent 5,413,774 in view of Tickner US Patent 4,265,251.

5. Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. As the initial matter, applicant's arguments against the references individually are not persuasive because one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, the rejection is based on the combined teachings of the reference, not merely individual teachings of the references.

6. Applicant has argued that Schneider does not teach C<sub>4</sub>F<sub>10</sub>, rather octafluorocyclobutane which has the molecular formula C<sub>4</sub>F<sub>8</sub>. (see arguments at page 2, 4<sup>th</sup> para.). In response, Examiner states that Applicant statement is not accurate. Schneider on col 14, lines 45 and line 68, specifically claims C<sub>4</sub>F<sub>10</sub>, which is perfluorobutane. Therefore, Schneider provides ample teaching for the use of C<sub>4</sub>F<sub>10</sub>.

7. Applicant then argues that Schneider mentions gas mixtures in general terms but never teaches any mixture containing fluorocarbon gas. (see arguments at page 2, last para.). In response Examiner states that Schneider clearly claims **gas mixtures** employing **perfluorocarbon gases** such as perfluoromethane, perfluoroethane, perfluorocyclobutane and perfluorbutane. These gases are fluorocarbon gas. Thus, Schneider teaches gas mixtures containing at least one fluorocarbon gas.
8. Applicant further argues that the uses of gaseous mixtures are not exemplified in Schneider (see arguments the entire page 3). Applicant is reminded that the instant rejection is employs a *prima facie* obviousness analysis, not anticipation. Therefore, the rejection is based on what would one of ordinary skill in the art have concluded having Schneider's teachings in possession. Since Schneider clearly envisions gaseous mixtures comprising at least one fluorocarbon gas, Applicant's arguments against Schneider's lack of gaseous mixtures in his examples are not found persuasive.
9. Applicant also argues that Tickner makes absolutely no showing that oxygen, nitrogen and Freons are substantially interchangeable or are functional equivalents. Applicant then alleges that the statement is not true. (see Arguments at page 4, 2<sup>nd</sup> and 3<sup>rd</sup> para.). As the initial matter, Examiner has argued in the previous Office Action that the gases of Tickner are **art recognized functional equivalents**. Such statement does not mean that the gases under questions are simply equivalent gases. Examiner has pointed out that the gases recited in

Tickner would functionally provide the same results when used in contrast medium compositions.

10. Aside from not providing any evidence in support of the allegations against the functional equivalency of the recited gases in Thickner, Applicant fails to provide any evidence of unexpected results in general. As recited in the previous Office Action, Tickner teaches methods of ultrasound imaging using gas containing microbubbles (abstract, col 7, lines 11-54). Tickner also teaches that although the preferred gas is carbon dioxide, however, other gases such as Freons and oxygen may be used in his contrast agents (col. 6, lines 63-67). Examiner has then viewed such gases to be **art recognized functional equivalents**, because they provide similar function when employed for the purposes of ultrasound imaging. That said, one of ordinary skill in the art in possession of Tickner would have had an understanding that when such gases are used for ultrasound imaging, they would provide better images than when such gases are not used for the same process of ultrasound imaging.

11. Moreover, the use of patents as references is not limited to what patentees describe as their own inventions or to problems with which they are concerned; they are part of literature of the art, relevant for all they contain. *In re Lemelson*, 158 USPQ 275 (CCPA 1968). As it has been held "[A]ll of the disclosures in a reference must be evaluated for what they fairly teach one of ordinary skill in the art." *In re Boe*, 355 F.2d 961, 148 USPQ 507 (CCPA 1966). This includes implicit teachings of patents as references, because they are part of the literature of the art, relevant for all they contain.

12. Accordingly, one of ordinary skill in the art in possession of Tickner would have at least recognized one common property among such gases when they are employed as contrast agent, and that is their boiling temperature in relationship to the body temperature. Attention is drawn to the page 10, Exhibit 1, of the instant Office Action. Exhibit #1 displays the boiling points for all the gases taught by the Tickner reference and its relationship with body temperature. Accordingly, it is evident to one of ordinary skill in the art in possession of Tickner that all such gases have a boiling point below body temperature. Therefore, one of ordinary skill in the art would have recognized that for the purposes of ultrasound imaging, the recited gases in Tickner should share at least one similar feature. They should all possess boiling points below body temperature. Subsequently, Applicant's allegation that Tickner does not show functional equivalents is simply inaccurate.

As stated in the previous Office Action, absence of showing unexpected results, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute one of air or nitrogen gases in Schneider's microvesicles with oxygen and create a microvesicle that contains pefluorobutane and oxygen, because as shown by Tickner, oxygen is considered art recognized equivalents to suitable gases enumerated by Schneider. Here, all that has taken place is the substitution of oxygen in place of a fluorocarbon gas in Schneider's gaseous mixture. Since Tickner sets forth that oxygen and freons are expected to provide the same function, as they are art recognized equivalents, the ordinary skill in the

art would have had a reasonable expectation of success in mixing perfluorobutane with oxygen to produce a gaseous microvesicles.

13. Claims 1-6, 9-10, 13-15, 17-18, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider in view of Unger US Patent 5,205,290.

14. Applicant's arguments with respect to this rejection have been fully considered but are not persuasive.

Applicant first argues that Unger is used for CT imaging not ultrasound. (see Arguments at page 6, 1<sup>st</sup> para.). Applicant is thus appearing to be arguing that Unger and Schneider are nonanalogous art. In response, Examiner states that it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the particular problem was whether Oxygen and Perfluorobutane can be mixed together for *in vivo* application.

15. Examiner states that the fact that Unger has used its composition for CT scanning is not in dispute. Actually, Examiner acquiesced to such short coming of Unger at page 7 of the Office Action filed on October 22, 2003. The use of oxygen and perfluorobutane for ultrasound imaging has already been established by Schneider which is the primary reference in this rejection. For example, Schneider states at col 5, lines 50-56 that gases such as air, nitrogen and the like have been used in ultrasound imaging. Aside from the point that air, itself, contains oxygen, one of ordinary skill in the art in possession of Schneider would



have understood that oxygen is one of such gases because nearly 10 years earlier, Tickner (cited above) disclosed such knowledge in his patent.

Therefore, the teachings of Schneider merely lacked the specific use of oxygen with perfluorobutane in a gaseous mixture *in vivo*. Unger was used to show that mixing oxygen and perfluorobutane for *in vivo* use had already been achieved. Thus, since Examiner viewed the use of gaseous mixture for imaging purposes reasonably pertinent to the problem that applicant was concerned in the instant application, Examiner's reliance on Unger is reasonable as a basis for the rejection under question. Accordingly, the rejection is deemed to be proper and is hereby maintained.

### **Conclusion**

No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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